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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,150	03/17/2005	Takeshi Kawazoe	2005_0459A	2807

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
10/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/528,150	KAWAZOE ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on August 3, 2010. Claim(s) 5-7 are pending and are examined herein.

Response to Arguments

Applicant's arguments with respect to the 103(a) rejection of claims 5-7 as being unpatentable over Konishi (US Patent No. 5,916,918) of record in view of Cappelli-Schellpfeffer (WO 01/70210 A2) of record have been fully considered but are not persuasive.

Applicant argues that "Konishi et al. disclose a treatment on open wound stage, while C-S disclose treatment on the stage of healed wound, namely the stage after scar or keloid formation. Thus, the combination of Konishi et al. and C-S, as purported by the Examiner, is untenable as the methods refer to distinct stages of treatment."

In response to this argument, Examiner respectfully notes that a set forth on record, Konishi teaches topically applying acetylsalicylic acid to an open wound. The C-S reference was employed to show that acetylsalicylic acid is effective for treating hypertrophic scar or keloid which is already formed, therefore one of ordinary skill in the art would expect with a reasonable degree of success that if that ointment is on the wound has closed then it would be effective in the course of therapy for an open wound. Thus based on the foregoing reasons, the instant rejection is hereby maintained.

Applicant further argues that "C-S does not disclose that acetylsalicylic acid is effective for treating hypertrophic scar or keloid which is already formed, or for inhibition of keloid and/or hypertrophic scar formation, with any working example. Specifically, acetylsalicylic acid was never topically administered to the patients in order to treat a scar or a keloid. In fact, C-S reveals that even when acetylsalicylic acid is orally administered to the patient suffering from post-operative scar, acetylsalicylic acid is not effective and therefore, salicylic acid-treatment is further necessary."

Examiner has fully considered this argument, however, it is respectfully noted that C-S specifically teaches a topical method for treating keloids using acetylsalicylic acid (page 13, lines 23-25). Although there may not be a working example of such, it would nonetheless provide enough motivation for one to at least try.

Thus based on the foregoing reasons, the instant rejection is hereby maintained.

For Applicant's convenience, the rejections of the previous office action are included in the Final Office action below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konishi (US Patent No. 5,916,918) of record in view of Cappelli-Schellpfeffer (WO 01/70210 A2) of record.

Konishi teaches application of topical preparation containing acetylsalicylic acid in a concentration of 0.1 to 10% by weight to an injured region of skin, specifically in a rat model of bedsore and a rat model of ambustion and burn, and have found that it showed remarkable remedy of the injured tissues in those injuries and inhibited the formation of crust even in a deep skin injury as reached to the muscular layer but instead promoted the formation of granulation tissue and epidermal tissue. Besides, it has been found that when acetylsalicylic acid was orally administered in an amount of 15-75 mg/kg/day to a rat skin-deficient model, it showed the same or similar effects as the above-mentioned topical preparation. Moreover, it has also been found that when

the above topical preparation was applied to a hardly curable bedsore in human patients, there have been observed remarkable reduction of injured area and remedy of wound in all patients. In the treatment of ambustion and burn, it showed remarkable recovery of skin injuries in addition to the known analgesic effects of acetylsalicylic acid. The therapeutic effects will be expected in every skin injuries (column 1, line 55-column 2, line 8).

Konishi teaches that the invention is provides a method for the treatment of skin injuries, especially hardly curable injuries such as bedsore by applying a topical preparation comprising acetylsalicylic acid to the injured region of skin or by administering orally a drug comprising acetylsalicylic acid (column 2, lines 10-23).

Konishi teaches the topical preparation of the present invention contains 0.05 to 15% by weight, preferably 0.1 to 10% by weight, more preferably 0.2 to 8% by weight, of acetylsalicylic acid based on the whole weight of the preparation (column 2, lines 54-58).

Konishi teaches several examples wherein acetylsalicylic acid is topically applied to an open wound and remarkable therapeutic effects were observed (see experiments 1-5).

Konishi teaches that the therapeutic effects were evaluated by measuring the size in both of long and short diameters of the injured region to calculate the area, and then the change of area of injured region was calculated (column 8, lines 6-20).

Konishi does not specifically teach treating keloid or hypertrophic scar formation per se.

Cappelli-Schellpfeffer teaches methods and compositions for improving the size and appearance of a healed wound, which may be a scar such as, a hypertrophic scar, a keloid, Dupuytren's contractures, ache scars, fibrotic scars, and reactive scars. Cappelli-Schellpfeffer teaches a topical method, which includes administering to an individual having a healed wound or scar a therapeutically effective amount of a cyclooxygenase inhibitor directly on the surface of the scar (page 13, lines 23-25). Note that acetylsalicylic acid is taught as a cyclooxygenase inhibitor (page 9, column 4-6).

Furthermore, Cappelli-Schellpfeffer teaches that by "improving" the size and appearance of a healed wound or a scar is meant to alleviate, either partially or completely, symptoms such as pain, tingling, itching, burning, discoloration; reducing the size of a scar; reducing surface irregularities; reducing the accumulation of fibrous tissue; and/or partially or completely eliminating the scar (page 11, line 23- line 27).

Additionally, Cappelli-Schellpfeffer teaches the composition is used to relieve or to prevent a condition of scar irritation, in particular in a case wherein scar irritation leads to symptoms including itching, and to a patient's self-inflicted mechanical action of scratching, which can result in further scar irritation, and possible contamination and invasion of the scar with native skin organisms (page 12, line 28-page 12, line 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed topical application of acetylsalicylic acid in the treatment of open wound skin injuries as taught by Konishi and also employed such compositions to treat potential keloids and hypertrophic scars in a course of therapy of a wound or dermal injury. The motivation, provided by Cappelli-Schellpfeffer, teaches that

acetylsalicylic acid is effective for treating hypertrophic scar or keloid on a closed wound, therefore one of ordinary skill in the art would expect with a reasonable degree of success that if said ointment is effective on a wound which has closed, as taught by Cappelli-Schellpfeffer and an open wound, as taught by Konishi, then it would be effective in the course of therapy of the wound.

Thus based on the foregoing arguments the instant claims are deemed unpatentable over the cited art.

Conclusion

Claims 5-7 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627